

RESPONSE

I. Status of the Claims

Claim 1 has been cancelled without prejudice or disclaimer. Claims 2 and 3 are allowed. New claims 4, 5 and 6 have been added to better claim the present invention. Claims 2-6 are therefore pending.

II. Support for the Amended Specification and Claims

Claim 4 has been added to better claim the present invention. New Claim 4 is supported by the specification as originally filed with particular support being found in original Claim 1 and the sequence listing.

Claim 5 has been added to better claim the present invention. New Claim 5 is supported by the specification as originally filed with particular support being found on or about page 13 lines 21-27.

Claim 6 has been added to better claim the present invention. New Claim 6 is supported by the specification as originally filed with particular support being found on or about page 13, lines 27-33.

As claims 4, 5 and 6 are fully supported by the specification, the sequence listing and claims as originally filed, they do not constitute new matter. Entry therefore is respectfully requested.

III. Rejection of Claim 1 Under 35 U.S.C. § 101

The Action rejects Claim 1 under 35 U.S.C. § 101 allegedly because the claimed invention lacks patentable utility. Applicants respectfully disagree.

The Action alleges that Applicant is well aware that 24 bases are not sufficient to encode any product with function, Applicants respectfully disagree. However, as Claim 1 has been cancelled, in order to advance this application towards allowance, this rejection has been rendered moot.

Applicants further submit that as claims 4-6 read on molecules with a well-recognized function, rejection under 35 U.S.C. § 101 would be unwarranted.

Therefore, due to cancellation of Claim 1, the present rejection of the pending claims under 35 U.S.C. § 101 has been avoided. Applicants, therefore, respectfully request withdrawal of the pending rejection.

IV. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

The Action also rejects Claims 1 under 35 U.S.C. § 112, first paragraph, allegedly since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. Applicants respectfully disagree, however, for as Claim 1 has been cancelled, this rejection has also been rendered moot. Again, Applicants believe that as claims 4-6 read on full-length molecules with a well-recognized function, rejection under 35 U.S.C. § 112, first paragraph, would also be unwarranted.

Therefore, Applicants submit that the rejections of the pending claims under 35 U.S.C. § 112, first paragraph have been avoided. Thus, Applicants respectfully request that the rejection be withdrawn.

V. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects Claim 1 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse.

35 U.S.C. § 112, first paragraph, requires that the specification contain a written description of the invention. The Federal Circuit in *Vas-Cath Inc. v. Mahurkar* (19 USPQ2d 1111 (Fed. Cir. 1991); “*Vas-Cath*”) held that an “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*.” *Vas-Cath*, at 1117, emphasis in original. However, it is important to note that the above finding uses the terms reasonable clarity to those skilled in the art. Further, the Federal Circuit in *In re Gosteli* (10 USPQ2d 1614 (Fed.

Cir. 1989); “*Gosteli*”) held:

Although [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.

Gosteli at 1618, emphasis added. Additionally, *Utter v. Hiraga* (6 USPQ2d 1709 (Fed. Cir. 1988); “*Utter*”), held “(a) specification may, within the meaning of 35 U.S.C. § 112 ¶1, contain a written description of a broadly claimed invention without describing all species that claim encompasses” (*Utter*, at 1714). Therefore, all Applicants must do to comply with 35 U.S.C. § 112, first paragraph, is to convey the invention with reasonable clarity to the skilled artisan.

Further, the Federal Circuit has held that an adequate description of a chemical genus “requires a precise definition, such as by structure, formula, chemical name or physical properties” sufficient to distinguish the genus from other materials. *Fiers v. Sugano*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993; “*Fiers*”). *Fiers* goes on to hold that the “application satisfies the written description requirement since it sets forth the . . . nucleotide sequence” (*Fiers* at 1607). In other words, provision of a structure and formula - the nucleotide sequence - renders the application in compliance with 35 U.S.C. § 112, first paragraph.

More recently, the standard for complying with the written description requirement in claims involving chemical materials has been explicitly set forth by the Federal Circuit:

In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. *Univ. of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Thus, a claim describing a genus of nucleic acids by structure, formula, chemical name or physical properties sufficient to allow one of ordinary skill in the art to distinguish the genus from other materials meets the written description requirement of 35 U.S.C. § 112, first paragraph. As further elaborated by the Federal Circuit in *Univ. of California v. Eli Lilly and Co.*:

In claims to genetic material ... a generic statement such as ‘vertebrate insulin cDNA’ or ‘mammalian insulin cDNA’, without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition.

It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art cannot, as one can do with a fully described genus, visualize or recognize the identity of members of the genus. (Emphasis added)

Thus, as opposed to the situation set forth in *Univ. of California v. Eli Lilly and Co.* and *Fiers*, the nucleic acid sequences of the present invention are not distinguished on the basis of function, or a method of isolation, but in fact are distinguished by structural features - a chemical formula, *i.e.*, the *sequence itself*.

Using the nucleic acid sequences, or amino acid sequences, of the present invention (as set forth in the Sequence Listing), the skilled artisan would readily be able to distinguish the claimed nucleic acids, or amino acids, from other materials on the basis of the specific structural description provided. Polynucleotides comprising 24 consecutive nucleic acids of the nucleotide sequence of, for example, SEQ ID NO:1 or a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2, are within the genus of the instant claims, while those that lack this structural feature lie outside the genus. Thus those of skill in the art would have known how to make and use the invention as claimed in original Claims 1-2.

However, as Claim 1 has been cancelled, this rejection has also been rendered moot. Again, Applicants believe that as claims 4-6 read on full-length molecules with a well-recognized function, rejection under 35 U.S.C. § 112, first paragraph, would also be unwarranted. Therefore, Applicants submit that the rejections of the pending claims under 35 U.S.C. § 112, first paragraph have been avoided. Thus, Applicants respectfully request that the rejection be withdrawn.

VI. Rejection of Claims Under 35 U.S.C. § 102(b)

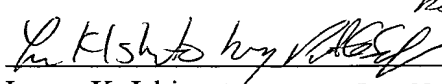
The Action next rejects claims 1-2 under 35 U.S.C. § 102(b), as being anticipated by Hillier, *et al.* (EST Database, Accession No. W90174, July 1996). Once again, as Claim 1 has been cancelled its rejection has been rendered moot. Furthermore, new claims 4-6 describe longer molecules and Hillier, *et al.* (EST Database, Accession No. W90174, July 1996) would not properly anticipate longer molecules. Applicants therefore respectfully request withdrawal of the rejection.

VII. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Monshipouri have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

October 31, 2003
Date

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